UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WISCONSIN
MILWAUKEE DIVISION

JAMES J. DANIEL, Plaintiff, v. WRIGHT MEDICAL TECHNOLOGY, INC., Defendant.	))))))))))	Case No. _____ **JURY TRIAL DEMANDED**

COMPLAINT FOR DAMAGES

Plaintiff James Daniel ("Plaintiff Daniel," "Plaintiff") files this Complaint for Damages and Jury Trial Demand against Defendant Wright Medical Technology, Inc. ("Wright" or "Wright Medical"), a Delaware corporation whose principal place of business is in Memphis, Shelby County, Tennessee, respectively showing the Court the following:

NATURE OF ACTION

1. This is a complaint for damages associated with metal wear debris, corrosion and resultant metal ions from failed Wright Medical Conserve® metal-on-metal hip implants.

2. For many years, Defendant has known its hip replacement device – the Wright Medical Conserve® Total Hip System ("Conserve® Total Hip System," "Conserve® Device," or the "Device") – was prone to fretting and corrosion and had

a propensity to fail within a few years of implantation despite that hip implant devices typically last up to twenty years or more. The articulating pieces (femoral ball and cup) of Defendant Wright's Device is comprised of a cobalt and chromium ("CoCr") alloy. As designed, the Device's metal-on-metal components generate metal debris, corrosion and metal ions, which cause dangerously elevated blood levels of CoCr ions, adverse tissue reactions, pseudotumors, necrosis, bone loss and other adverse medical events in patients. As a result of the Device's defects and Wright's tortious acts/omissions, Plaintiff James Daniel and many other patients who received these Devices endured unnecessary pain and suffering; debilitating lack of mobility; and a subsequent surgery to replace the defective Device, giving rise to more pain and suffering, a prolonged recovery time, and an increased risk of complications and death from surgery.

PARTIES

3. At all relevant times hereto, Plaintiff James Daniel was and is an adult resident and citizen of the State of Wisconsin. Plaintiff resides in Kenosha, Kenosha County, Wisconsin.

4. Defendant Wright Medical Technology, Inc. ("Wright" or "Wright Medical") is a Delaware corporation, with its principal place of business at 1023 Cherry Road, Memphis, Shelby County, Tennessee 38117, and is registered to do business in the State of Tennessee, and at all times relevant hereto did business in

the State of Tennessee and in the State of Wisconsin. Defendant Wright is a wholly owned subsidiary of Wright Medical Group, Inc. Wright may be served with process by serving its registered agent for service, Corporation Service Company, at 8040 Excelsior Drive, Suite 400, Madison, Wisconsin 53717.

5. Defendant Wright was, at all relevant times, engaged in the business of designing, developing, manufacturing, distributing, selling, marketing and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, various prosthetic orthopedic products, including the Conserve® Total Hip System at issue in this civil action.

STATEMENT OF JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a) as the parties are citizens of different States, and the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

7. Venue is proper in this district pursuant to 28 U.S.C. § 1391, *et seq*., because a substantial part of the events giving rise to this claim occurred in Wisconsin and in this district.

8. Defendant is subject to the Court's personal jurisdiction because at all times relevant hereto Defendant transacted business in and continues to transact business in the State of Wisconsin. Defendant has sufficient minimum contacts with

Wisconsin such that exercise of jurisdiction over Defendant would not offend traditional notions of fair play and substantial justice.

9. At all times relevant hereto, Wright advertised, promoted, marketed, sold and/or distributed the defective Conserve® Total Hip System, including the Conserve® femoral head and Conserve® acetabular cup, throughout the United States, including the State of Wisconsin.

FACTUAL ALLEGATIONS

A. The Device and Its Regulatory History

10. Between approximately 2003 and 2011, Wright marketed and sold several metal-on-metal ("MoM") hip replacement devices, two of which were the Conserve® Total Hip Device and the Conserve® Resurfacing Device.

11. The Conserve® Total Hip Device was developed for use in total hip replacements and included four metal components: (1) a stem inserted into the patient's femur, (2) a neck that connects the stem to (3) a BFH metal femoral head (which Wright called the "BFH" – for "big femoral head" - and the A-Class BFH), and (4) an acetabular shell.

12. The Conserve® Total Hip Device, like all hip implant products, is regulated by the Food and Drug Administration ("FDA") as a Class III Medical Device, pursuant to 21 U.S.C. § 360c and 21 C.F.R. § 888.3330, Prosthetic Devices.

13. For Class III devices, the FDA requires compliance with either the Pre-Market Approval process ("PMA") or the section 510(k) substantial equivalence pre-market clearance process before a manufacturer can market and sell a total hip replacement or hip resurfacing device in the United States.

14. On July 1, 2002, the FDA gave Wright 510(k) clearance to market the Metal Transcend Articulation System (Larger Sizes), which was re-branded the "Conserve" and is referred to herein as the Conserve® Total Hip Device.

15. Several different acetabular shells were developed for use with the Conserve® Devices, including: the "Thick Shell" (with a 5 mm wall thickness), the "Thin Shell" (with a 3 to 4 mm wall thickness), the "Spiked Shell" (with spikes), and the "HA Shell" (with a hydroxyl apatite coating to facilitate bony ingrowth). (K041425 (Thick Shell); K031963 (Spiked Shell); K042530 (HA Shell); K113322 (Thin Shell)).

16. Wright obtained FDA 510(k) clearance to market the Spiked Shell (in 2003), the HA Shell (in 2004), and the Thick Shell (in 2004). (*See id.*)

17. Wright also received FDA 510(k) clearance to market the A-Class femoral head in 2005 (K051348).

18. But, despite that more than 90% of the acetabular shells that Wright marketed and sold with Conserve® Devices between 2003 and 2011 were Thin Shells, Wright failed to seek FDA 510(k) clearance to market the Thin Shell until

November 2011, and did not receive any FDA clearance to market the Thin Shell until February 2012. (K113322).

19. By February 2012, Wright had no market for the Conserve® Hip Devices and had, in fact, stopped marketing the Conserve® Devices in June 2011.

B. Wright's History with the Device

20. Wright purchased Orthomet, Inc. to obtain a stake in the new and profitable metal-on-metal hip replacement device market. In the early 1990s, after establishing itself in small joint orthopedics and total knee replacements, Wright decided to move into the hip replacement market.

21. Wright purchased Orthomet, Inc. in December 1994 because Orthomet was in the development stages of two MoM hip systems: the Transcend Metal-on-Metal Total Hip System (which eventually became the Conserve® Total Hip Device) and the Conserve® Resurfacing Device.

22. Orthomet hired Dr. Harlan Amstutz, a McKee fellow, a MoM proponent, and the designer of the Tharies (a previous failed Zimmer resurfacing device), as the lead surgeon designer for the Conserve® Devices.

23. As of the mid-1990s, the majority of the devices available for hip replacement utilized a press fit metal shell with porous coating and a separate polyethylene liner with a ceramic or metal head. Although Wright recognized that this construct was seeing good success, Wright also recognized the substantial

market potential for a metal-on-metal articulation in hip replacement as an alternative to using polyethylene.

24. In the late 1990s, Wright hoped to be the only orthopaedic medical device company to offer a total resurfacing device in the United States, but because the McMinn System was already on the market in European countries, Wright needed to move quickly to get the Conserve® Resurfacing Device on the U.S. market.

25. Wright considered the Conserve® Resurfacing Device as a product that had the potential to capture a significant market share in the United States.

26. In July 1993, Al Lippincott from Orthomet prepared a product initiation request for a metal-on-metal system, recognizing that Orthomet had an opportunity to establish itself as a forerunner in orthopedic research with development of a new metal-on-metal hip system and could gain substantial market share of the hip implant market.

27. At that time, Orthomet recognized that several companies, including Sulzer, DePuy, Smith & Nephew, Zimmer, and others were currently re-evaluating metal-on-metal systems.

28. In November 1995, Wright Medical employees Al Lippincott and Robert L. Conta, then Vice President of Development & Technology, attended a four-day conference, chaired by Dr. Harlan C. Amstutz, and organized by the Joint Replacement Institute in Los Angeles. There, industry professionals and experts

held a four day MoM summit, open discussion, debate, and dialogue about MoM hips, addressing the technology, the clinical significance of wear debris, implant tribology, the need for changes, the types of studies needed to make sure they were safe, and similar issues.

29. Conclusions drawn at the MoM summit included the possibility that MoM is not a good alternative to polyethylene, and that more needed to be learned and studied regarding the risks associated with MoM bearing surfaces.

30. In 1995, prior to marketing the Conserve® Devices, Wright was notified by leading surgeons and designers of a number of major MoM risks that demanded further testing, such as: metal toxicity, inflammation, bone loss, allergic reaction, local tumor formation, systemic effects, soft tissue necrosis, osteolysis, and blood-borne metal ions.

31. Yet Wright did not conduct any studies to investigate these known risks prior to marketing its Conserve® Devices and components, and has never performed any tests related to most of the "hot-button" issues that forced surgeons to reject metal-on-metal implants in the 1970s.

C. The Conserve Thin Shell Never Received PMA Approval and Was a Regulatory and Clinical Failure

32. In 2000, Wright initiated clinical studies of its Conserve® Plus Hip Resurfacing device, which was conducted under Investigational Device Exemption ("IDE")[1] G990328.

33. In September 2003, Wright submitted a Pre-Market Approval (PMA) submission, #P030042, for its Conserve® Plus Resurfacing Hip System, which utilized a Thick Shell (with a 5mm wall thickness).

34. Following a January 2004 inspection related to the Conserve® Plus Resurfacing Hip System PMA #P030042 and IDE study G990328, Wright was cited for failure to properly monitor studies and failure to report adverse events.

35. Dr. Harlan Amstutz was similarly cited.

36. In July 2004, Wright was placed on Integrity Hold for regulatory violations related to the Conserve® Plus Resurfacing Hip System PMA #P030042 and IDE study G990328.

37. Due to the FDA's Integrity Hold, Wright could not submit products for approval without an independent third party first reviewing its submission. Wright contracted with Phiama Consulting and Health Policy Associates to conduct a

[1] An IDE allows a non-cleared, non-approved medical device to be used as part of a clinical study to collect data as to safety and efficacy to support a PMA application or 510(k) premarket notification submission to the FDA.

review of device submissions to ensure the overall quality of Wright's future US regulatory submissions.

38. The FDA continued to institute an Integrity Hold for Wright's products for over three years until September of 2007.

39. Wright further sought to add a Thin Shell (with a 3.5mm wall thickness) to its Resurfacing PMA submission. But the clinical data from Wright's Conserve® Plus Resurfacing Device's Thin Shell IDE cohort showed such high failures that Wright withdrew the Thin Shell from its PMA application at least twice between 2003 and November 2011, due to the high failure rate and lack of follow-up.

40. Wright's Conserve® Resurfacing Device IDE clinical study results utilizing the Thin Shell showed a revision rate - a failure of Conserve® devices requiring surgery to replace the components - of 18.6% of the patients at 24+ months.

41. Nonetheless, and despite its IDE clinical studies demonstrating the Thin Shell's clinical failure, from 2003 through 2011, Wright marketed the Conserve® Devices utilizing the Thin Shell – a device never PMA approved and not 510(k) cleared by the FDA until 2012.

42. Wright never informed surgeons or patients that its own clinical studies revealed that the Thin Shell caused an extraordinarily high revision rate of 18.6% at the 24 plus month period.

43. The FDA found Wright had under-reported Thin Shell failures and that the Thin Shell's revision rate exceeded 33% in Wright's clinical studies.

D. Wright Obtained Pre-Marketing 510(k) Clearance For Some – But Not All – Conserve® Components

44. Wright sought FDA clearance to market its Conserve® Total Hip Device through the 510(k) "substantial equivalence" process.

45. A 510(k) notice is a premarket submission in which the manufacturer claims the submitted device is substantially equivalent to a predicate device that is already on the market.

46. Wright represented that its first MoM device, the Transcend (later renamed "Conserve"), was substantially equivalent to the previously marketed McKee-Farrar device.

47. The McKee-Farrar device, a MoM design first used in 1960, was removed from the market in the 1970s because of problems with osteolysis, inflammation, cystic responses, cyto-toxic metal ions and tissue reactions necessitating revisions in 50% of the implants, according to the designer, Dr. George McKee.

48. Due to the poor clinical results of the McKee-Farrar device, the FDA refused to allow it as an acceptable predicate design and demanded testing for Wright's Metal Transcend Articulation System (1997) submission (K964627).

49. The 1997 510(k) submission for the Metal Transcend Articulation System K964627 was never cleared for marketing.

50. In 2001, Wright obtained 510(k) clearance for its modular Metal Transcend Articulation System, consisting of three components a screw-fit metal shell (K004043), metal liner, and metal head intended for use in total hip arthroplasty.

51. In 2002, Wright received 510(k) clearance to market the monoblock Metal Transcend Articulation System (Larger Sizes) for use in total hip arthroplasty, utilizing a one-piece (or "monoblock") Thick Shell (with a 5mm wall thickness) and a metal femoral head based on its purported equivalence to the Metal Transcend Articulation System (K004043), (K021349).

52. In August 2005, Wright received FDA clearance to market the A-Class Conserve® Total Femoral Head (K051348).

53. As Wright touted its "soon to be approved resurfacing device" to surgeons and customers, Wright marketing personnel and agents realized that the Conserve® could be sold as a total hip process and also had great promise for huge profits as a total hip replacement.

E. Wright Dodged the FDA Through Inappropriate Use of a "Letter to File," In Lieu Of the 510(k) Process, For the Conserve® Thin Shell

54. In 2003, Wright introduced its Conserve® Thin Shell (with a 3.5mm wall thickness) to its Conserve® Devices without notification to FDA or 510(k) clearance, let alone PMA.

55. To avoid the FDA's premarket approval ("PMA") and 510(k) processes, Wright used a "Letter to File," an internal decision to market the Thin Shell without notice to FDA. This regulatory shortcut for the Conserve® Thin Shell was based on the supposed "Minor Modification" to other substantially similar devices on the market.

56. Wright marketed the Conserve® Thin Shell for more than eight (8) years without FDA notice or review, despite substantial clinical evidence collected through its Conserve® Plus Resurfacing Thin Shell IDE study that the Conserve® Thin Shell had poor outcomes.

57. Wright later acknowledged that a design change affecting safety and efficacy to a device is not appropriate for an internal Letter to File.

58. A wall thickness change from 5mm for the Conserve® Thick Shell to 3.5mm for the Conserve® Thin Shell is a modification that affects the safety and effectiveness of the Conserve® Devices, yet Wright did not conduct any clinical

testing beyond the failed IDE study to evaluate whether the change from a Thick Shell to a Thin Shell affected safety or efficacy.

59. Because the change from the 5mm Conserve® Thick Shell to the 3.5mm Conserve® Thin Shell was significant, and Wright did not account for the risk from this change in its Letter to File MM03-0004, Wright's decision to utilize a Letter to File in lieu of 510(k) clearance was incorrect.

60. Instead of utilizing a unilateral Letter to File, Wright was required to obtain 510(k) clearance to legally market the Conserve® Thin Shell.

F. Wright Belatedly Obtained (Post-Market) 510(k) Clearance for the Thin Shell

61. In September 2011, Wright finally acknowledged that the Thin Shell design marketed under the February 13, 2003 Letter to File "Minor Modification" presented a new worse case (thinner shell) and therefore should have been submitted to FDA for review under the 510(k) process before marketing and sale of the Conserve® Thin Shell began in 2003.

62. As Wright consistently collected information questioning the safety and efficacy of its Conserve® Devices and their components, it continued to promote the Conserve® Hip Devices using false and misleading data.

63. For example, Wright continued to advertise that the Conserve® A-Class Device generated fewer metal ions even though its own studies suggested the opposite conclusion.

G. Wright Aggressively Marketed the Device as Appropriate for Active Patients

64. The Conserve® Hip Device's use of BFH technology and A-Class metal was marketed to surgeons as capable of increasing range of motion, decreasing dislocation issues, lower wear, and biocompatibility, all of which were presented as significant benefits for young and active recipients as well as anyone possessing a high-demand hip.

65. When Wright marketed the Conserve® Total Hip Device to surgeons, it claimed the device was ideal for young, very active patients because post-hip-replacement, those patients could be as active as they wanted to be, with a greater range of motion without dislocation or wear related concerns.

66. Wright hired professional tennis player and celebrity Jimmy Connors as a spokesperson of Wright to endorse and market the Conserve® Devices. Wright represented that with his new Conserve® Device, Mr. Connors was back on the tennis court in 6 weeks, a result that should be expected by patients who were implanted with the Conserve® Devices.

67. In marketing the Conserve® Devices, Wright used marketing materials (websites, journal ads, brochures, pamphlets, patient testimonials, endorsements, newspaper articles and other PR) aimed at surgeons and younger, more active consumers who wanted to return to the following strenuous physical activities, among others, that Wright advertised:

(a) Surfing;

(b) Yoga

(c) Skiing;

(d) Martial Arts, including competition levels;

(e) Hockey;

(f) Ice Skating;

(g) Motorcycling;

(h) Horseback rides;

(i) Tennis;

(j) Golf;

(k) Soccer;

(l) Football;

(m) Mountain climbing;

(n) Running, including marathons and triathlons;

(o) Hiking;

(p) Biking, including trail riding;

(q) Swimming;

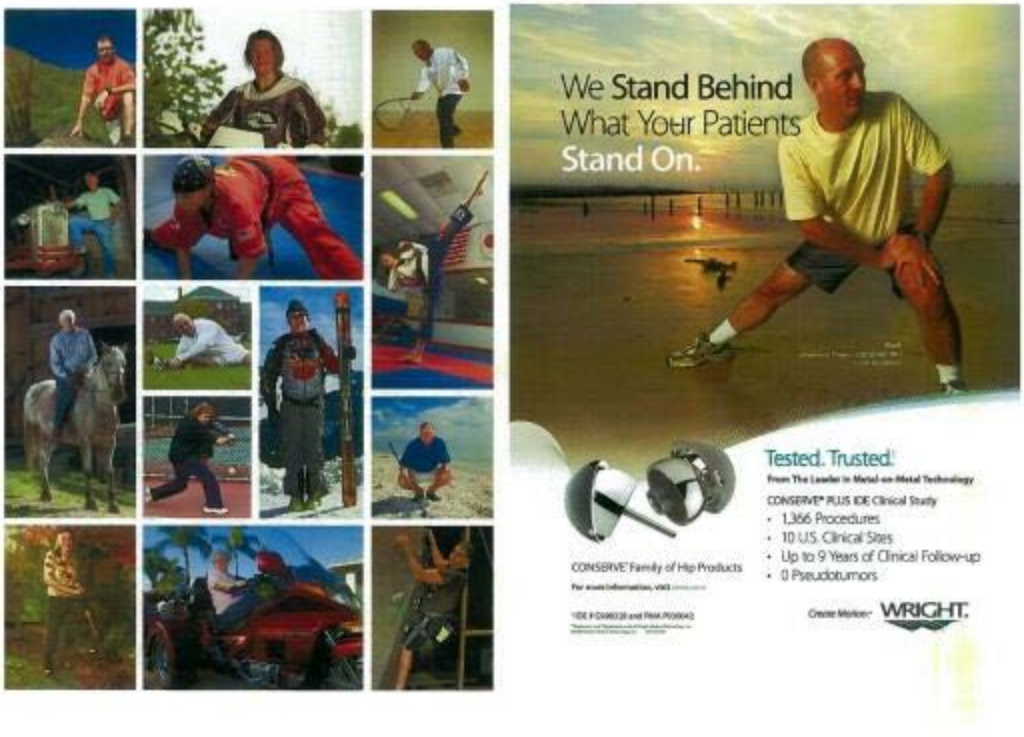
(r) Racquetball;

(s) Active military duty;

(t) Competitive wrestling; and

(u) Kayaking.

68. Representative ads include:



69. Wright's marketing of the Conserve® Devices included the following testimonials from patients and surgeons:

(a) "Before the surgery I couldn't run. I couldn't play soccer. Now, there's no pain in the joint at all. Hip replacement gave me my life back."

(b) "Because the procedure allows him to be as aggressive as he wanted to be, there -- there was no reason for me to tell him to hold back."

(c) "Some patients have been able to pursue more vigorous activities, including martial arts, hockey, running marathons, even climbing Mount Kilimanjaro."

(d) "Wright Medical which makes the Conserve® Total hip said the hip replacement lasts 25 to 30 years."

(e) "Just six weeks after his [minimally invasive surgical] hip procedure, [Jimmy Connors] completed filming for a tennis training DVD."

70. When Wright marketed the Conserve® Total Hip Device to surgeons, it claimed that the device was fully biocompatible and that the device had good longevity.

71. Wright also knew researchers were advising against using MoM implants in female patients and its own internal information showed dangerously high revision rates in women.

72. Nonetheless, Wright continued to aggressively market its products for use by women.

73. Wright's partners at the Oxford Group (Richie Gill) reported unfavorable findings on the Conserve® Devices, including a strong suggestion of pseudotumors associated with MoM wear and recommended that Conserve® Devices not be implanted in women.

74. Wright also knew researchers were advising against putting the similar DePuy ASR devices in women, and that its partners in Oxford planned to publish a paper warning against MoM hip resurfacing in young females.

75. But Wright continued to market the Conserve® Devices to younger, active lifestyle women; including younger women engaging in competitive martial arts, ice skating, running, dirt biking, even those who desired to be "physically aggressive."

H. Wright Minimized the Known Risk of Elevated Metal Ion Levels

76. Wright never provided any information to surgeons regarding what was considered a dangerous cobalt or chromium ion level for a patient with a MoM Conserve® Device.

77. Wright never told surgeons about the risks and problems associated with its Conserve® Total Hip Device, including metallosis.

78. The biggest concern Wright faced in selling the Conserve® Devices was the issue of metal ion release, as surgeons' top concern was the effect of metal ions.

79. Before, during and after Wright designed, developed, manufactured, marketed and sold its Conserve® Devices, Wright knew of the principles and concerns associated with MoM devices generating wear debris and releasing toxic cobalt and chromium heavy metal ions.

80. Despite its knowledge that metal ions associated with MoM hips presented significant risks, Wright worked to convince surgeons that metal ions were not an issue with the Conserve® Devices.

81. Wright was aware as of 1998 that research indicated that at three years post-implantation, there was as much as a 5X increase in the concentration of chromium in the serum and 8X increase in the concentration of chromium in the urine for MoM versus metal-on-polyethylene ("MoP") hip replacement devices.

82. No later than 2003, Wright recognized that metallic particulate debris is approximately an order of magnitude smaller than polyethylene debris, so that even low rates of volumetric wear could lead to a larger numbers of particles.

83. Before, during and since Wright designed, developed, manufactured, marketed and sold its Conserve® Devices, Wright knew that surgeons were concerned about metal ion release and its effects on the body.

84. Before, during and since Wright designed, developed, manufactured, marketed and sold its Conserve® Devices, Wright knew patients with MoM hip

implants exhibited 10 times higher concentrations of metal ions compared to patients with MoP hip implants.

85. Before, during and since Wright designed, developed, manufactured, marketed and sold its Conserve® Devices, Wright knew that Cobalt and Chromium ions cause metallosis, necrosis, inflammation, bone loss, cup loosening, aseptic, lymphocyte-dominated vasculitis-associated lesions ("ALVAL") and pseudotumors.

86. Before, during and since Wright designed, developed, manufactured, marketed and sold its Conserve® Devices, Wright knew there were reports that Cobalt and Chromium ions have toxic effects.

87. Before, during and since Wright designed, developed, manufactured, marketed and sold its Conserve® Devices, Wright had available literature that indicated that combined ion levels of Cobalt and Chromium of 5 parts per billion ("ppb") generated immune suppression.

88. Before, during and since Wright designed, developed, manufactured, marketed and sold its Conserve® Devices, Wright had literature available that indicated that cobalt and Chromium ion levels at 7 ppb were considered elevated and indicated that a patient and her physicians should consider revision.

89. Before, during and since Wright designed, developed, manufactured, marketed and sold its Conserve® Devices, Wright did not know how to evaluate the significance of Cobalt and Chromium metal ion levels.

90. Before, during and since Wright designed, developed, manufactured, marketed and sold its Conserve® Devices, Wright did not know what levels of Cobalt and/or Chromium ion levels would or could cause harm.

91. Before, during and since Wright designed, developed, manufactured, marketed and sold its Conserve® Devices, Wright did not know the long-term consequences to patients of exposure to Cobalt and Chromium ions.

92. Despite concerns for the effect, danger, and damage potentially caused by Cobalt and Chromium ions, and despite not knowing what ion levels would be safe, acceptable, injurious or dangerous, Wright did not undertake any biocompatibility or any other testing to determine whether metal-ion release from the Conserve® Device was safe.

93. Before, during and since Wright designed, developed, manufactured, marketed and sold its Conserve® Devices, Wright never tried to determine what levels of Cobalt or Chromium are toxic.

94. Before, during and since Wright designed, developed, manufactured, marketed and sold its Conserve® Devices, Wright did not do testing to assess the risk of metal ion release or the effects of metal ion release on the human body.

95. Before, during and since Wright designed, developed, manufactured, marketed and sold its Conserve® Devices, Wright did not conduct any clinical studies to determine or evaluate the local or systemic effect of Cobalt and Chromium ions.

96. Before, during and since Wright designed, developed, manufactured, marketed and sold its Conserve® Devices, Wright never did any testing to determine the risk posed to patients from exposure to Cobalt and Chromium ions.

97. Wright recognized that surgeons' biggest concern about the use of MoM hip devices was the generation of metal ions. Therefore, Wright had to convince surgeons that metal ions would not be an issue with the Conserve® Hip Implant.

98. Minimizing metal ions was such a huge concern for Wright in marketing its Conserve® Devices that it focused extensively on minimizing metal-ion concerns through publications and speakers.

99. Wright utilized consulting surgeon Key Opinion Leaders' ("KOL's") presentations to orthopaedic groups and peer reviewed data, paid-for scientific data publications, celebrity endorsements, and sales representative training, among other avenues, to falsely assuage metal-ion concerns and market the Conserve® Devices.

100. Throughout the Conserve® Devices' marketed lifespan, Wright consistently boasted in its marketing that metal ions from its Conserve® Devices were/are harmless.

101. In fact, Wright's OrthoRecon marketing department disregarded field concerns over metal ion issues and told surgeons that Wright had no negative reports for metal ion issues.

102. Wright did not inform surgeons or potential patients of its concerns or lack of knowledge regarding the release of Cobalt and Chromium ions from Conserve® Total Hip Implants, despite acknowledging that surgeons and patients were concerned about the issue.

103. In fact, Wright, as early as 2002, told its sales personnel, who were in direct contact with surgeons, that, "the effects of metal ion release are known and have been demonstrated to be safe," which was the equivalent of decriminalizing metal ions.

I. Wright Studied Metal Ions Solely to Support A-Class Sales

104. Wright decided to run metal ion studies, not to determine safe levels of metal ions, but instead to be able to market that its Conserve® Total Hip Devices utilizing an A-Class femoral head (which utilized a "harder" Cobalt and Chromium metal alloy than the standard femoral head) would generate fewer metal ions than Wright's competitor and thus Wright could sell the A-Class device at a higher price.

105. Wright aggressively marketed its A-Class metal, which it contended resulted in less wear, less metal debris and, by implication, fewer metal ions.

106. Wright utilized taglines such as "Reduced Wear, Increased Longevity," "A-Class Never Compromise," and "A Hip for Life" in marketing its A-Class BFH technology with the Conserve® Total Hip Device.

107. Wright ignored that its A-Class metal ions studies were a failure, demonstrating that less wear did not translate into fewer metal ions.

108. Even Wright's internal metal ion studies conducted by key Conserve® Device KOLs and surgeon consultants such as Paul Beaule, M.D., Josh Jacobs, M.D., and Koen DeSmet, M.D., could not prove that the generation of less wear debris correlated with fewer metal ions, despite Wright's touting this alleged A-Class design advantage.

J. Wright's Representations and Reasonable/Justifiable Reliance

109. Wright also told James A. Shapiro, M.D. ("Dr. Shapiro") that the cobalt chromium cup should last longer than a traditional Metal/Polyethylene liner, and that there were no known issues associated with cobalt and chromium ions.

110. Based on Dr. Shapiro's information from Wright about the benefits of the Conserve® Total Hip Device and no known risks from metal ions, and his recommendation, Plaintiff decided to proceed with elective left total hip arthroplasty

("THA") to implant a left side MoM Conserve® Total Hip Device, utilizing the Thin Shell, and not another type of available hip such as the MoP or ceramic/polyethylene.

111. On February 17, 2006, Dr. Shapiro implanted a Wright Conserve® system in Plaintiff James Daniel's left hip, including the following components: A Wright Conserve® Plus Head, Size 52mm and a Conserve® Plus Cup (Thin Shell), Size 58 mm.

112. On or about January 9, 2018, Plaintiff Daniel experienced failure with elevated metal ion levels and increasing pain in Plaintiff's left hip with activity.

113. On or about January 9, 2018, Plaintiff Daniel entered the hospital for left hip revision surgery due to a failed left total hip arthroplasty.

114. Intraoperatively, Stephen L. Nord, M.D. ("Dr. Nord") noted abundant blackened stained and/or abnormal tissue, which are signs of a metallosis reaction requiring removal of the device and discolored reactive tissue.

115. Dr. Nord's findings indicated that Plaintiff's left Conserve® Total Hip Device had failed due to metallosis, i.e., acute onset of pain, fluid buildup, tissue changes, etc.

116. Since Plaintiff's Conserve® left hip revision surgery, Plaintiff is still restricted in activities, and had to give up activities such as walking moderate distances without hip pain, and has physical limitations when exercising, and avoids vigorous exercising.

117. Numerous physicians who previously had Wright consulting contracts have testified that, had they been aware of the risks back in the early to mid-2000s when they first started implanting the Conserve® hip replacement Devices, they would not have chosen those implants.

118. Presently, Dr. Shapiro is aware of risks associated with the Conserve® hip implant such as adverse reaction, metal ions, metallosis, necrotic tissues that he was not aware of at the time of implantation of Plaintiff's device.

119. If Dr. Shapiro had known in February of 2006 what he knows now about the risks from metallosis from the Conserve® Total Hip Device, he would not have implanted it in Plaintiff.

120. Wright marketed that the Conserve® Devices experienced acceptably low failure rates, despite real revision rates reported via medical device registries and surgeons' actual revisions demonstrating that the Conserve® Devices had a statistically unacceptably high failure rate.

121. Wright has never reported the Conserve® Devices' high failure rates to surgeons, to patients with implanted Conserve® Devices, or to the public.

122. Wright continued to market the Conserve® Devices even as its own KOLs, consultants, researchers and surgeons were reporting high failure rates and other problems with the implant, and even discontinuing use of the Conserve® Devices.

123. Wright received complaints and reports of unacceptable failure rates of its Conserve® Devices from Brad Penenberg, M.D., a Wright KOL, consultant, Peer-to-Peer trainer, premier Los Angeles surgeon and Conserve® Devices royalty recipient, who concluded the Conserve® Device was not a successful product and stopped using them because of problems he experienced with the Conserve® Devices starting in 2007.

124. Although Patrick Fisher, Director of Hip Marketing admitted that it was significant that Wright's most prominent, highest paid consultant thought the Conserve® Device was a failure, Wright never shared that information with other surgeons or the public.

125. C. Lowry Barnes, M.D., from Little Rock, Arkansas, a Wright KOL, consultant, and Peer-to-Peer trainer, complained about the Conserve® Devices and stopped using them.

126. G. Lynn Rasmussen, M.D., and his partner, Kent Samuelson, M.D., both Wright KOLs, consultants and high-volume Conserve® Device implant surgeons in Salt Lake City, Utah, stopped using the Conserve® Devices because of unacceptably high failure rates.

127. Dr. Andersen, a Wright KOL, product champion, Conserve® Devices royalty recipient from Germantown, Wisconsin, had problems with the Conserve® Device post-Plaintiff's implant surgery that were known to Wright.

128. Michael Dunbar, M.D., from Halifax, Nova Scotia, reported a 20% Conserve® Device failure rate to Wright in March 2008 and discontinued using the Conserve® Devices.

129. Edward Sparling, from Vancouver, Washington, a high volume Wright surgeon, KOL, consultant and IDE participant, reported problems with the Conserve® Devices to Wright and stopped using them in April 2009.

130. Richard Weiner, M.D., from Palm Beach, Florida, a high-volume Wright surgeon, reported high Conserve® Device failure rates to Wright, advised Wright that the Conserve® Devices should never be implanted in women, and stopped using the Conserve® Devices.

131. Raymond Corpe, M.D., from Augusta, Georgia, a Wright KOL, consultant and high-volume Wright implant surgeon, complained to Wright about the Conserve® Devices and stopped using the Conserve® Devices.

132. Vincent Fowble, M.D., from Jupiter, Florida, a Wright KOL, consultant and high-volume Wright implant surgeon, complained to Wright about the Conserve® Devices and stopped using the Conserve® Devices.

133. Kace Ezzet, M.D., from La Jolla, California, reported high failure rates to Wright and as a result, stopped using the Conserve® Devices.

134. Milton Smit, from Bradley, Illinois, a Wright KOL, consultant and high-volume Wright implant surgeon, complained to Wright about the Conserve® Devices' high failure rates and stopped using the Conserve® Devices.

K. Wright Ignored and Isolated Complaining Physicians

135. Wright created a smokescreen by isolating and blaming surgeons who reported failures, telling reporting surgeons that no other surgeons around the country were having failures.

136. When distributor David J. Burke reported an increase in failed Conserve Devices to Wright, Wright told him that they were not having problems with the device and questioned whether the surgeons at issue had followed proper surgical protocol.

137. Wright did not reveal these surgeon complaints and decisions not to use the Conserve® Devices to other surgeons, Wright's complaint department, Wright sales personnel or distributors, patients, or the public.

138. Internally, Wright's less-than-robust complaint department continued to receive complaints from all over the country regarding metal debris, reactions, pseudotumors and ALVAL associated with the Conserve® Devices.

139. Wright received registry data that showed increasing failures of the Conserve® Devices, including: a 2008 Australian Bone & Joint Registry Report of a 16.4% failure rate; a 2009 UK National Joint Registry Report of a 7.4% failure

rate; a 2011 UK National Joint Registry Report of a 8.35% failure rate; and a 2012 UK National Joint Registry Report of an 8.52% failure rate at five years.

140. In response to an Association of British Healthcare Industries ("ABHI") position statement on MoM hip bearings, Wright acknowledged it knew from the start that the clinical performance of early MoM devices "frequently and matter-of-factly mentioned tissue reactions, metallosis, and revisions due to pain."

PLAINTIFF'S INJURIES AND DAMAGES

PLAINTIFF JAMES DANIEL'S LEFT SIDE CONSERVE® HIP

141. On or about February 17, 2006, Plaintiff James Daniel had a Wright Conserve® artificial hip implanted in his left hip (a/k/a the "Index Surgery") in a procedure known as a total hip arthroplasty (or "THA").

142. Orthopedic surgeon James A. Shapiro, M.D., performed the left Index Surgery during which he implanted the Conserve® Total Hip System in Plaintiff Daniel.

143. Plaintiff Daniel's right Index Surgery was performed at Kenosha Medical Center, 6308 8th Avenue, Kenosha, Wisconsin 53143.

144. Dr. Shapiro did not breach any generally accepted standard of care in the field of orthopedic surgery in his care and treatment of Plaintiff Daniel or negligently cause any injury to Plaintiff in any of the following respects:

(a) in the care or treatment that he provided to Plaintiff Daniel prior to beginning the hip implant surgery;

(b) in the hip implant surgery he performed on Plaintiff; or

(c) in the care or treatment that he provided to Plaintiff, subsequent to Plaintiff's hip implant surgery.

145. Based upon the patient population that Wright intended its artificial hip devices to be implanted in, at the time of Plaintiff Daniel's left side Index Surgery, he was an appropriate patient to be implanted with the Conserve® Total Hip System.

146. Dr. Shapiro recommended the Conserve® Total Hip System to Plaintiff Daniel and indicated that the Device was appropriate for him.

147. Plaintiff Daniel reasonably relied upon Dr. Shapiro in deciding to proceed with hip replacement surgery and have the Conserve® Total Hip System implanted.

148. Before or during the course of Plaintiff Daniel's left side Index Surgery, Defendant arranged for the Conserve® Total Hip System that was implanted in Plaintiff Daniel to be delivered to Kenosha Medical Center and/or Dr. Shapiro for implantation in Plaintiff Daniel.

149. Defendant, directly or through its subsidiaries or affiliates, designed, manufactured, distributed and sold in the United States various prosthetic orthopedic

devices, including the Conserve® Total Hip System implanted in Plaintiff Daniel during the left side Index Surgery, which included the following components:

- Wright Conserve Plus Head;
- Wright Conserve Plus Cup.

These Wright components are hereinafter collectively referred to as the left "Conserve® Total Hip System" or the "Device."

150. At the left hip Index Surgery, each of the components of Plaintiff Daniel's Conserve® Total Hip System was in substantially the same condition in all relevant respects as when they left Defendant's control.

151. At all times relevant hereto, Plaintiff Daniel used the Conserve® Total Hip System implanted during the left Index Surgery in a normal and reasonably foreseeable manner.

152. On or about January 9, 2018, Plaintiff Daniel reported to Dr. Nord for revision surgery of his failed left hip prosthesis ("Revision Surgery"). Dr. Nord recommended the revision surgery after Plaintiff Daniel presented with significant pain.

153. Plaintiff Daniel's left hip Revision Surgery was necessary because the Device failed due to adverse tissue reaction to metal debris, corrosion, and resultant metal ions.

154. The Revision Surgery was performed by Dr. Nord. During the left hip Revision Surgery, Dr. Nord removed failed components of Plaintiff Daniel's left side Conserve® Total Hip System.

155. But for the fact that the left-side Conserve® Total Hip System had generated metal debris, metal ions and corroded causing it to fail and injure Plaintiff, Plaintiff Daniel's Device was not otherwise in need of revision.

156. On or about January 9, 2018, it was discovered that the left side Device failed due to metal debris, corrosion and resultant metal ions, due to the MoM design between the articulating surfaces, causing continuing and otherwise irreversible physical injury to Plaintiff Daniel.

157. On or about January 9, 2018, the Conserve® Total Hip System implanted in Plaintiff James Daniel's left hip was discovered to have failed as a direct and proximate result of the actions, conduct, negligence, and breach of duties of the Defendant, as alleged in this Complaint.

158. The Conserve® Total Hip System (and its components), to include the Device implanted in Plaintiff Daniel's left side was not merchantable, and was unreasonably dangerous for its intended and/or reasonably foreseeable uses in that:

(a) it was and is unreasonably dangerous under Wisconsin's product liability law as a result of one or more or a combination of the following:

(i) the Conserve® Total Hip Implant System was manufactured/designed in such a manner as to generate CoCr metal debris, corrosion and resultant CoCr metal ions, thereby increasing the potential for failure;

(ii) the components were manufactured/designed in such a way as to make the articulating surfaces of the components susceptible to fretting and corrosion, thereby increasing the potential for failure; and

(iii) there may be other conditions or defects yet to be determined.

(b) it was dangerous to an extent beyond which could be contemplated by the ordinary consumer with the ordinary knowledge common to the community as to its characteristics in that:

(i) the ordinary consumer would not contemplate that the Device would create metal debris, metal ions and corrosion or that premature revision surgery would become necessary approximately eleven (11) to twelve (12) years after implantation; and

(ii) the ordinary consumer would not contemplate that the ordinary activities of daily living would result in the Device releasing harmful metal ions and metal debris in the consumer's body that caused adverse tissue reactions and other medical complications.

159. The Device was not tested in design and development under conditions that were known would be encountered in the normal in vivo patient environment over substantial periods of time.

160. The Device was not tested in design and development under the normal in vivo patient environmental conditions that were known would be encountered during normal use of the Device.

161. The Device was not tested for the FDA Section 510(k) Premarket Notification Process under conditions that were known would be encountered in the normal in vivo patient environment.

162. Wright's testing of the Device did not adhere to or meet FDA guidance.

163. Wright knew the Device was failing from fretting and corrosion of the articulating surface prior to the day Wright provided its 510(k) submission to the FDA.

164. Wright knew the Device was failing at higher than expected rates from fretting and corrosion of the articulating surface prior to the date of its implantation in Plaintiff Daniel during the left-side Index Surgery.

165. Wright knew the Device was failing at higher than expected rates due to fretting and corrosion prior to the date of Plaintiff Daniel's left hip Revision Surgery, during which it was discovered that Plaintiff suffered from adverse tissue reaction to metal debris, metal ions and corrosion.

166. Prior to the right hip Index Surgery, Wright did not warn patients, surgeons, customers, or its sales representatives/distributors that the Device was known to be failing from metal debris and corrosion at higher than expected rates.

167. On or about January 9, 2018, Plaintiff James Daniel discovered the Device implanted in his left side failed due to adverse tissue reaction from metal debris, metal ions and corrosion as a result of one or more or a combination of the foregoing unreasonably dangerous conditions.

168. As a direct and proximate result of the failure of the left-side Conserve® Total Hip System, Plaintiff Daniel has sustained injuries and damages, including, but not limited to:

(a) undergoing surgery to remove and replace the failed prosthesis;

(b) past and future pain and anguish, both in mind and in body;

(c) permanent diminishment of his ability to participate in and enjoy the affairs of life;

(d) medical bills associated with the revision surgery and recovery therefrom;

(e) future medical expenses;

(f) loss of enjoyment of life;

(g) loss of past and future earnings and earning capacity;

(h) disfigurement; and

(i) physical impairment.

FEDERAL STATUTORY AND REGULATORY REQUIREMENTS

169. Pursuant to federal law, a medical device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. 21 U.S.C. § 351.

170. Pursuant to federal law, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. 21 U.S.C. § 352.

171. Pursuant to federal law, manufacturers are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to prevent introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any medical device may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. Federal law also mandates that the FDA establish regulations requiring a manufacturer of a medical device to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to

remedy a violation of federal law by which a device may present a risk to health. 21 U.S.C. § 360(i).

172. Pursuant to federal law, the Secretary of Health and Human Services may prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device, but not including an evaluation of the safety or effectiveness of a device), packaging, storage and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with federal law.

173. The regulations requiring conformance to good manufacturing practices are set forth in 21 C.F.R. § 820, *et seq.* As explained in the Federal Register, because the Current Good Manufacturing Practice (CGMP) regulations must apply to a variety of medical devices, the regulations do not prescribe the details for how a manufacturer must produce a device. Rather, the quality system regulations provide a framework of basic requirements for each manufacturer to use in establishing a quality system appropriate to the devices designed and manufactured and the manufacturing processes employed. Manufacturers must adopt current and effective methods and procedures for each device they design and

manufacture to comply with and implement the basic requirements set forth in the quality system regulations.

174. Pursuant to 21 C.F.R. § 820.1(c), the failure to comply with any applicable provision in Part 820 renders a device adulterated under section 501(h) of the Federal Drug & Cosmetic Act ("the Act"). 21 U.S.C. § 351.

175. Pursuant to 21 C.F.R. § 820.5, each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device designed or manufactured. "Quality system" means the organizational structure, responsibilities, procedures, processes and resources for implementing quality management. 21 C.F.R. § 820.3(v).

176. Pursuant to 21 C.F.R. § 820.22, each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.

177. Pursuant to 21 C.F.R. § 820.30(a), each manufacturer shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

178. Pursuant to 21 C.F.R. § 820.30(d), each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements.

179. Pursuant to 21 C.F.R. § 820.30(e), each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development.

180. Pursuant to 21 C.F.R. § 820.30(f), each manufacturer shall establish and maintain procedures for verifying the device design to confirm that the device design output meets the design input requirements.

181. Pursuant to 21 C.F.R. § 820.30(g), each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots or batches, or their equivalents. Design validations shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions.

182. Pursuant to 21 C.F.R. § 820.30(h), each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

183. Pursuant to 21 C.F.R. § 820.30(i), each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review and approval of design changes before their implementation.

184. Pursuant to 21 C.F.R. § 820.70(a), each manufacturer shall develop, conduct, control and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Such process controls shall include:

(a) documented instructions, standard operating procedures ("SOPs") and methods that define and control the manner of production;

(b) monitoring and control of process parameters and component and device characteristics during production;

(c) compliance with specified reference standards or codes;

(d) the approval of processes and process equipment; and

(e) criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.

185. Pursuant to 21 C.F.R. § 820.70(b), each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure.

186. Pursuant to 21 C.F.R. § 820.70(c), each manufacturer shall establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to have an adverse effect on product quality, including

periodic inspection of environmental control system(s) to verify that the system, including necessary equipment, is adequate and functioning properly.

187. Pursuant to 21 C.F.R. § 820.70(e), each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on produce quality.

188. Pursuant to 21 C.F.R. § 820.70(g), each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirement and is appropriately designed, constructed, placed and installed to facilitate maintenance, adjustment, cleaning and use.

189. Pursuant to 21 C.F.R. § 820.70(h), each manufacturer shall establish and maintain procedures for the use and removal of manufacturing material which could reasonably be expected to have an adverse effect on product quality to ensure that it is removed or limited to an amount that does not adversely affect the device's quality.

190. Pursuant to 21 C.F.R. § 820.70(i), when computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol.

191. Pursuant to 21 C.F.R. § 820.72, each manufacturer shall ensure that all inspection, measuring and test equipment, including mechanical, automated or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked and maintained.

192. Pursuant to 21 C.F.R. § 820.75(a), where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. "Process validation" means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications. *See* 21 C.F.R. § 820.3(z)(1).

193. Pursuant to 21 C.F.R. § 820.75(b), each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met. Each manufacturer shall ensure that validated processes are performed by qualified individuals.

194. Pursuant to 21 C.F.R. § 820.90, each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements.

195. Pursuant to 21 C.F.R. § 820.100, each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

(a) analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product or other quality problems;

(b) investigating the cause of nonconformities relating to product, processes and the quality system;

(c) identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

(d) verifying or validating the corrective and preventative action to ensure that such action is effective and does not adversely affect the finished device;

(e) implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

(f) ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

(g) submitting relevant information on identified quality problems, as well as corrective and preventative actions, for management review.

196. Upon information and belief, Wright's Conserve® Total Hip System is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it failed to meet established performance standards and/or the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. *See* 21 U.S.C. § 351.

197. Upon information and belief, Wright's Conserve® Total Hip System is misbranded because, among other things, it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. § 352.

198. Upon information and belief, Wright's Conserve® Total Hip System is adulterated pursuant to 21 U.S.C. § 351 because Wright failed to establish and maintain CGMP for its Conserve® Total Hip System, including components, in accordance with 21 C.F.R. § 820, *et seq.*, as set forth above.

199. Upon information and belief, Wright failed to establish and maintain CGMP with respect to the quality audits, quality testing and process validation for its Conserve® Total Hip System, including its components.

200. As a result of Wright's failure to establish and maintain CGMP as set forth above, Wright's Conserve® Total Hip Systems were defective and failed, resulting in injuries to Plaintiff James Daniel.

201. If Wright had complied with the federal requirements regarding CGMP, Wright's Medical Conserve® Total Hip System would have been manufactured and/or designed properly such that it would not have resulted in injuries to Plaintiff Daniel.

202. Plaintiff Daniel's injuries were both factually and proximately caused by the Defendant's defective Conserve® Total Hip System.

203. Plaintiff Daniel's injuries were both factually and proximately caused by the Defendant's unreasonably dangerous Conserve® Total Hip System.

204. Plaintiff Daniel further shows that he is entitled to recover for all noneconomic and compensatory damages allowed by law, including, but not limited to, pain and suffering for all pain and suffering that he has incurred as a result of the defective product, the follow-up surgery, rehabilitation, and constant pain that occurs as a result of the failure of the Device.

LIABILITY

COUNT 1 – NEGLIGENT DESIGN AND FAILURE TO WARN OR INSTRUCT

205. Plaintiff incorporates by reference as if fully set forth herein the facts alleged in paragraphs 1-204 of this Complaint.

206. Wright owed a duty of reasonable care to the general public, including Plaintiff James Daniel, when it designed, manufactured, assembled, inspected, tested, marketed, placed into the stream of commerce, and sold the Conserve® Total

Hip System, to protect users from an unreasonable risk of harm when using the Device for its intended purpose, in a reasonably foreseeable manner.

207. Wright breached this duty by designing, manufacturing, assembling, inspecting, testing, marketing, distributing and selling the Conserve® Total Hip System in a defective and unreasonably unsafe condition including, but not limited to, its foreseeably appreciated risk of harm from the device's propensity for fretting, corrosion and failure. A reasonably prudent medical device manufacturer would not have acted in this manner.

208. Likewise, Wright owed Plaintiff a duty of reasonable care to discover the defects and to inform and/or warn him or his implanting surgeon of the defects once they were discovered, and Defendant failed to warn of the dangers inherent in the reasonably foreseeable use of the Conserve® Total Hip System, further placing Plaintiff at risk for harm and injury.

209. Wright failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, warning, marketing, promotions and distribution of the Conserve® Total Hip System. Wright knew or should have known that these products cause significant bodily harm and were not safe for use by consumers, and/or through failure to comply with federal requirements.

210. Wright, furthermore, in advertising, marketing, promoting, packaging and selling the Device negligently misrepresented material facts regarding its safety, efficacy, and fitness for human use by claiming the Device was fit for its intended purpose when, in fact, it was not.

211. Wright, in advertising, marketing, promoting, packaging and selling the Device, negligently misrepresented material facts regarding its safety, efficacy and fitness for human use by claiming the Device had been adequately and reliably tested when, in fact, it had not.

212. Wright, in advertising, marketing, promoting, packaging and selling the Device, negligently misrepresented material facts regarding its safety, efficacy and fitness for human use by claiming the risk of serious adverse events and/or effects from the Device was comparable to that of other hip replacements systems when, in fact, it was not.

213. Wright, in advertising, marketing, promoting, packaging and selling the Device, negligently misrepresented material facts regarding its safety, efficacy and fitness for human use by claiming the Device had not caused or contributed to serious adverse events and/or effects requiring the premature revision surgery to replace and/or repair the Device when, in fact, it had.

214. Wright knew or had reason to know that Plaintiff Daniel, as a member of the general public for whose use the Device was placed into interstate commerce, would be likely to use the Device in a manner described in this Complaint.

215. Wright knew or should have known of the dangers associated with the manner and circumstances of Plaintiff James Daniel's foreseeable use of the Device, which dangers would not be obvious to the general public.

216. Despite the fact that Wright knew or should have known that the Conserve® Total Hip System posed a serious risk of bodily harm to consumers, Wright continued to manufacture and market the Device for use by consumers and/or continued to fail to comply with federal requirements.

217. Wright knew or should have known that consumers such as Plaintiff Daniel would foreseeably suffer injury as a result of Wright's failure to exercise ordinary care as described above, including the failure to comply with federal requirements.

218. Wright's conduct, as described above, including, but not limited to, its failure to adequately test and warn as well as its continued marketing and distribution of the Conserve® Total Hip System when it knew or should have known of the serious health risks these Devices created and/or the failure to comply with federal requirements, was and is negligent.

219. As a direct and proximate result of Wright's negligence, including negligent testing, failure to warn and misrepresentations, Plaintiffs suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages and economic loss in the future.

220. As a direct and proximate result of Wright's negligence, Plaintiff suffered and will continue to suffer injuries, damages and losses, and are entitled to compensatory damages in an amount to be determined by the trier of fact.

221. Wright was negligent in the particulars set forth in this Complaint, and such negligence was a direct and proximate cause of the incident and injuries set forth herein.

COUNT 2 – STRICT PRODUCTS LIABILITY: DEFECTIVE DESIGN

222. Plaintiff incorporates by reference as if fully set forth herein the facts alleged in paragraphs 1-204 of this Complaint.

223. Plaintiff Daniel was damaged by the defective Conserve® Total Hip System.

224. Wright was engaged in the business of manufacturing, selling and distributing the Conserve® Total Hip System.

225. The Wright Conserve® Total Hip System used in Plaintiff Daniel's hip replacement surgery was supplied in a defective condition in its design, such that it

would generate metal debris, metal ion cast off and corrosion at the articulating surface, rendering it unreasonably dangerous.

226. Wright had a duty to place into the stream of commerce, manufacture, distribute, market, promote and sell the Conserve® Total Hip System so that it was neither defective nor unreasonably dangerous when put to the use for which it was designed, manufactured, distributed, marketed and sold.

227. On and prior to February of 2006 Wright was engaged in the business of designing, manufacturing, marketing, distributing and selling orthopedic hip implants and did design, manufacture, distribute, market and sell the Device.

228. Wright did in fact manufacture, sell, distribute, supply and/or promote the Device to Plaintiff Daniel and his implanting physician. Wright expected the Device it was selling, distributing, supplying, manufacturing and/or promoting to reach, and which did in fact reach, implanting physicians and consumers in the State of Wisconsin, including Plaintiff James Daniel and his implanting physician, without substantial change in the condition.

229. At the time the Device left the possession of Wright and the time the Device entered the stream of commerce, it was in an unreasonably dangerous or defective condition. These defects include, but are not limited to, the following:

(a) the Device was not reasonably safe as intended to be used;

(b) the Device had an inadequate design for the purpose of hip replacement;

(c) the Device contained unreasonably dangerous design defects, including an inherently unstable and defective design, to include the use of cobalt and chromium metal alloys (i.e. a CoCr modular head and CoCr acetabular cup) as the articulating surface, which resulted in an unreasonably high probability of early failure;

(d) the Device's unstable and defective design resulted in a hip prosthesis which had risks which exceeded the benefits of the medical device;

(e) the Device was not appropriately or adequately tested before its distribution; and

(f) the Device has an unreasonably high propensity for metal debris and fretting corrosion under normal and expected use of the Devices.

230. At the time of Defendant's initial design, manufacture, marketing and sale of the Device, a safer, feasible, alternative safer design for the Device was known and available to Wright, including, but not limited to, a titanium shell with a polyethylene liner acetabular cup design.

231. At the time of and subsequent to Wright's initial design, manufacture, marketing and sale of the Device, including prior to the time of Plaintiff Daniel's initial left hip implant surgery, Wright had the ability to eliminate the unsafe character of the Device without impairing its usefulness.

232. Wright's Conserve® Total Hip System Device, was, therefore, defective in design or formulation in that, when it left Wright's hands, the foreseeable risk of harm from the product exceeded or outweighed the benefit or utility of the Devices' particular design or formulation, and/or it was more dangerous than an ordinary consumer would expect, and/or it failed to comply with federal requirements for these medical devices.

233. The foreseeable risks associated with the design or formulation of the Wright Conserve® Total Hip System devices include, but is not limited to, the fact that the design or formulation of the Conserve® Total Hip System Device is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner, and/or it failed to comply with federal requirements.

234. As a direct and proximate result of Plaintiff Daniel's use of Wright's Conserve® Total Hip System Device, as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Wright and/or its failure to comply with federal requirements, Plaintiffs suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

235. As a direct and proximate result of Wright's defective products and tortious conduct as set forth herein, Plaintiff suffered and will continue to suffer

injuries, damages and losses, and are entitled to compensatory damages in an amount to be determined by the trier of fact.

236. The Conserve® Total Hip System's defective condition proximately caused Plaintiffs' damages.

COUNT 3 – STRICT PRODUCTS LIABILITY: MANUFACTURING DEFECT

237. Plaintiff incorporates by reference as if fully set forth herein the facts alleged in paragraphs 1-204 of this Complaint.

238. Plaintiff James Daniel was damaged by the defective Conserve® Total Hip System.

239. Wright was engaged in the business of manufacturing, selling and distributing the Conserve® Total Hip System.

240. Upon information and belief, Plaintiff alleges that the Device implanted during the index surgery did not conform to and/or deviated from Wright's intended design specifications and/or other typical units of the same product line in that the dangerous levels of metal ions, debris, and corrosion.

241. The Conserve® Total Hip System used in Plaintiff Daniel's left hip replacement surgery was supplied in a defective condition in its manufacture, such that it would generate metal debris, fretting and corrosion at the head-cup interface,

rendering it unreasonably dangerous for implantation in the body, contrary to Wright's design.

242. The Conserve® Total Hip Systems' defective condition proximately caused Plaintiff's damages.

COUNT 4 – STRICT PRODUCTS LIABILITY – FAILURE TO WARN

243. Plaintiff incorporates by reference as if fully set forth herein the facts alleged in paragraphs 1-204 of this Complaint.

244. Plaintiff Daniel was damaged by the defective Conserve® Total Hip System.

245. Wright was engaged in the business of manufacturing, selling, and distributing the Conserve® Total Hip System.

246. At all times relevant herein, Wright was engaged in the design, development, testing, manufacturing, marketing and sale of the Conserve® Total Hip System device.

247. Wright designed, manufactured, assembled and sold the Conserve® Total Hip System device to medical professionals and patients knowing that they would then be implanted in patients in need of a hip prosthesis.

248. Wright distributed and sold the Conserve® Total Hip System device in a condition such that when they left its place of manufacture, in their original form of manufacture, they included the defects described herein.

249. The Conserve® Total Hip System devices were expected to and did reach Plaintiff Daniel and his implanting surgeon, Dr. Shapiro, without substantial change or adjustment in their condition as manufactured and sold by Wright.

250. Defendant's Conserve® Total Hip System Device designed, developed, tested, manufactured, marketed and sold or otherwise placed into the stream of commerce by Wright were in a dangerous and defective condition and posed a threat to any user or consumer of the Conserve® Total Hip System device.

251. At all times relevant herein, Plaintiff Daniel was a person whom Wright should have considered to be subject to the harm caused by the defective nature of the Conserve® Total Hip System device.

252. Wright's Device was implanted and used in the manner for which it was intended.

253. This use has resulted in severe physical and emotional and other injuries to Plaintiff Daniel.

254. Wright knew or should have known through testing, adverse event reporting or otherwise that its Conserve® Total Hip System device created a high risk of bodily injury and serious harm.

255. Wright had a duty to warn its sales representatives/distributors, implanting surgeons such as Dr. Shapiro and patients such as Plaintiff James Daniel,

and Wright breached its duty in failing to provide adequate and timely warnings or instructions regarding its Conserve® Total Hip System device and its known defects.

256. Wright, furthermore, breached its duty to warn at pre-surgery and/or post-surgery by (a) failing to adequately communicate the warning to Defendant's sales representatives/distributors and/or to the ultimate users, i.e., Plaintiff James Daniel and/or his implanting physician; and/or (b) by failing to provide an adequate warning of the Device's potential risks.

257. Adequate efforts to communicate a warning to the ultimate users were not made by Wright (or its sales representatives/distributors) and, to the extent a warning was communicated by Wright, the warning was inadequate.

258. The warnings (pre-surgery and/or post-surgery) to Plaintiff Daniel and his implanting physician about the dangers the Devices posed to consumers were inadequate. Examples of the lack and/or inadequacy of Wright's warnings include, but are not limited to, one or more of the following particulars:

(a) the Device contained warnings insufficient to alert Plaintiff Daniel and Plaintiff's physicians as to the unreasonably high failure rate and propensity for generating metal wear debris, metal ion cast off and corrosion, associated with the Device, subjecting Plaintiff Daniel to risks which exceeded the benefits of the Devices;

(b) the Device contained misleading warnings emphasizing the efficacy of the Device while downplaying the risks associated with it, thereby making use of the Device more dangerous than the ordinary consumer would expect;

(c) the Device contained insufficient and/or incorrect warnings to alert consumers, including Plaintiff Daniel, through its prescribing physicians regarding the risk, scope, propensity, frequency, duration and severity of the adverse events associated with the Device;

(d) the Device's warnings and instructions did not disclose that they were inadequately tested;

(e) the Device's warnings and instructions failed to convey adequate post-marketing warnings regarding the risk, severity, propensity, frequency, scope and/or duration of the dangers posed by the Device; and

(f) the Device's instructions were insufficient to alert physicians and consumers to the dangers they posed and to give them the information necessary to avoid or mitigate those dangers.

259. Plaintiff Daniel used the Device for its intended purpose, i.e., hip replacement.

260. Plaintiff Daniel could not have discovered any defect in the Device through the exercise of due care.

261. Wright, as designer, developer, manufacturer, marketer and distributor of medical devices is held to the level of knowledge of an expert in the field.

262. Plaintiff Daniel and his implanting physician did not have substantially the same knowledge about the Device as Wright who was the designer, manufacturer, and distributor of the Device.

263. Wright reasonably should have known if its Device was unsuited for active individuals such as Plaintiff Daniel.

264. As a direct and proximate result of Wright's failure to adequately communicate a warning and/or failure to provide an adequate warning and other wrongful conduct as set forth herein, Plaintiff Daniel has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages, as set forth herein.

265. As a direct result of Wright's failure to warn and/or inadequate warning and Defendant's other tortious conduct, Plaintiff Daniel has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

266. As a direct and proximate result of Wright's failure to warn and/or inadequate warning and its other tortious conduct, as set forth herein, Plaintiff suffered and will continue to suffer injuries, damages and losses, and are entitled to compensatory damages in an amount to be determined by the trier of fact.

COUNT 5 – NEGLIGENT MISREPRESENTATION

267. Plaintiff incorporates by reference as if fully set forth herein the facts alleged in paragraphs 1-204 of this Complaint.

268. Wright had a duty to accurately and truthfully represent to the medical community, Plaintiff Daniel, and the public that the Conserve® Total Hip System had not been adequately tested nor found to be safe and effective for the treatment of patients requiring a hip replacement. Instead, Wright made representations about the Device that it, at a minimum, should have known to be false.

269. Wright negligently misrepresented to the medical community, including implanting orthopedic surgeon Dr. Shapiro, Plaintiff James Daniel, and the public that the Conserve® Total Hip System presented no risk or a low risk of unreasonable and dangerous adverse side effects.

270. Plaintiff and Plaintiff's implanting surgeon were not in a position to determine the truth or falsity of Wright's material representations regarding the safety and efficacy of its device, and reasonably and justifiably relied on said representations by Wright.

271. Had Wright accurately and truthfully represented to the medical community, Dr. Shapiro, Plaintiff Daniel, and the public the material facts that it knew or should have known regarding the risks of the Conserve® Total Hip System,

Plaintiff and/or Plaintiff Daniel's healthcare provider(s) would not have utilized the Device.

272. As a direct and proximate result of Wright's negligent misrepresentations, Plaintiff experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or other damages.

COUNT 6 – FRAUD BY CONCEALMENT

273. Plaintiff incorporates by reference as if fully set forth herein the facts alleged in paragraphs 1-204 of this Complaint.

274. Wright had a duty to accurately and truthfully represent to the medical community, Plaintiff Daniel, and the public that Wright Medical Conserve® Total Hip System had not been adequately tested and found to be safe and effective for the treatment of patients requiring a hip replacement. Instead, Wright knew, but deliberately failed to communicate this to Plaintiff Daniel or Plaintiff's surgeon.

275. Wright had a duty to inform, but fraudulently concealed from the medical community, including implanting orthopedic surgeon Dr. Shapiro, Plaintiff Daniel, and the public that the Wright Medical Conserve® Total Hip System had an

unreasonable and dangerous risk of generating metal debris and metal ions causing bodily injury.

276. Wright knew of the risk of metal debris and corrosion and resulting bodily injury present in the device implanted in Plaintiff, while neither Plaintiff nor Plaintiff's implanting surgeon had this information. Neither Plaintiff nor implanting surgeon could have discovered this information through reasonable diligence.

277. Wright had a duty to communicate the increased risk and known failures associated with the Device implanted in Plaintiff to Plaintiff and Plaintiff's surgeon.

278. Plaintiff and Plaintiff's surgeon justifiably relied upon Wright to communicate known risks and failures in both the decision to implant the device and follow up treatment after index surgery.

279. Had Wright accurately and truthfully represented to the medical community, Dr. Shapiro, Plaintiff Daniel, and the public the material facts that it knew regarding the risks of the Conserve® Total Hip System, Plaintiff and/or Plaintiff's healthcare provider(s) would not have utilized Wright's Conserve® Total Hip System.

280. Had Wright not fraudulently concealed the increased risk of metal debris, metal ions and corrosion, the dangers from corrosion and metal debris, the

known failures of the device from Plaintiff or Plaintiff's surgeon, Plaintiff's injuries would have been avoided or limited.

281. As a direct and proximate result of Wright's fraudulent concealments, Plaintiff experienced significant mental and physical pain and suffering, sustained permanent injury, underwent medical treatment and will likely undergo further medical treatment and procedures, suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or other damages.

COUNT 7 –FRAUDULENT MISREPRESENTATION

282. Plaintiff incorporates by reference as if fully set forth herein the facts alleged in paragraphs 1-204 of this Complaint.

283. Wright made false representations of material fact to Plaintiff and/or her healthcare providers as to the safety and efficacy of its Conserve® Total Hip System before it was selected and utilized in Plaintiff's replacement surgery.

284. Instead of disclosing the heightened risks of corrosion, failure, and permanent injury, Wright represented via printed literature and statements to surgeons:

(a) that there was no indication of an increased risk of adverse events due to metal-on-metal articulation-generated fretting and corrosion;

(b) that cobalt and chromium metal ions had been tested clinically;

(c) that the clinical testing had shown that exposure to cobalt and chromium metal ions had proved them to be safe;

(d) that cobalt-chromium articulating components resulted in less wear than metal-on-polyethylene and would last longer; and

(e) that the Conserve® Total Hip System, including its component parts, was safe and effective, and was safer and more effective than other treatments for hip replacements.

285. Wright knew that the above representations alleged in paragraph 284 were false, yet willfully, wantonly, and recklessly disregarded the inaccuracies in its representations.

286. Wright made these false representations with the intent of defrauding and deceiving the medical community (including implanting surgeon Dr. Shapiro, Plaintiff, and the public), and to induce the medical community, Plaintiff's implanting surgeon, Plaintiff and the public to utilize its Conserve® Total Hip System. Doing so constituted a callous, reckless, willful, depraved indifference, and/or intentional disregard of the health, safety, and welfare of Plaintiff and the public.

287. Plaintiff Daniel, and his implanting orthopedic surgeon Dr. Shapiro, reasonably and justifiably relied upon Wright's false representations of material fact in deciding to utilize the Conserve® Total Hip System.

288. Had Plaintiff or his healthcare providers known the true facts about the dangers and health risks of the Wright Conserve® Total Hip System, they would not have utilized the Device.

289. As a direct and proximate result of Wright's fraudulent conduct, Plaintiffs experienced significant mental and physical pain and suffering, sustained permanent injury, underwent medical treatment and will likely undergo further medical treatment and procedures, suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or other damages.

COUNT 8 – PUNITIVE DAMAGES

290. Plaintiff incorporates by reference as if fully set forth herein the facts alleged in paragraphs 1-204 of this Complaint.

291. Wright knew or should have known, in light of the surrounding circumstances, that its conduct would naturally and probably result in injury or damage and continued the conduct with malicious intent and/or in intentional disregard of the rights of Plaintiff. Accordingly, Plaintiff is entitled to an award of punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment and an award of damages against Wright, as follows:

(a) for special damages, to include past and future medical and incidental expenses, according to proof;

(b) for past and future loss of earnings and/or earning capacity, according to proof;

(c) for past and future general damages, to include pain and suffering, emotional distress and mental anguish, according to proof;

(d) for exemplary and punitive damages in an amount to be determined at trial;

(e) for pre-judgment and post-judgment interest;

(f) for the costs of this action, including reasonable attorneys' fees; and

(g) granting any and all such other and further legal and equitable relief as the Court deems necessary, just and proper.

A TRIAL BY JURY IS RESPECTFULLY DEMANDED.

Dated: December 23, 2020.

Respectfully submitted,

/s/ N. Kirkland Pope

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